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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

01083-T8907.CON

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on 1/15/2006

Signature Judy Anderson

Typed or printed name Judy Anderson

Application Number

10/806,669

Filed

3/22/2004

First Named Inventor

TRACY GIBBS

Art Unit

1655

Examiner

Meller, Michael V.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 44,989

☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34

David W. Osborne
Signature

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Typed or printed name

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Telephone number

1/15/2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*

☐ *Total of forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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REASONS FOR PRE-APPEAL BRIEF REVIEW

In the Office Action mailed July 13, 2006 (hereinafter, the "Office Action"), Claims 36-56, 62, and 64-67 were finally rejected. The claims were rejected as allegedly being obvious over U.S. Patent Nos. 6,103,756 to Gorsek (hereinafter "Gorsek"), or 5,785,977 to Breitbarth (hereinafter "Breitbarth"), taken with U.S. Patent Nos. 3,615,687 to Mochizuki (hereinafter "Mochizuki"), 6,534,063 to Fallon (hereinafter "Fallon"), 5,902,617 to Pabst (hereinafter "Pabst") or 4,378,434 to Prentice et al. (hereinafter "Prentice"), Chinese Publication no. 1096457 to Liang et al. (hereinafter "Liang"), U.S. Patent Nos. 5,597,585 to Williams et al. (hereinafter "Williams") or 6,020,351 to Pero (hereinafter "Pero"), 6,447,809 to Krumhar et al. (hereinafter "Krumhar"), 6,461,607 to Farmer (hereinafter "Farmer") or 5,759,520 to Sachetto (hereinafter "Sachetto"), 6,042,823 to Kimura et al. (hereinafter "Kimura"), and 6,451,341 to Slaga et al. (hereinafter "Slaga"). In the following discussion Applicant has focused on specific aspects of the claimed invention which are clearly not taught or suggested by the cited references. Additionally, the Applicant asserts that the Examiner has failed to set forth adequate motivation to combine the inordinate number of references. The presentation of the current arguments does not preclude Applicant from arguing additional deficiencies in the cited references and the office action during any later Appeal proceedings or prosecution.

The Claimed Invention

As recited in Claim 36, the present invention includes a nutrient absorption increasing composition that includes:

A nutrient absorption increasing composition comprising:

- a) an amount of *Aspergillus* derived protease having a protein hydrolyzing activity of from about 1,000 HUT, to about 60,000 HUT, and a calcium compound cofactor which provides calcium in a ratio of at least about 1 mg of calcium for every 1200 HUT of protease activity;
- b) an amount of an *Aspergillus* derived lipase having a lipid hydrolyzing activity of from about 10 LU to about 800 LU, and a zinc compound cofactor which provides zinc in a ratio of at least about 1 mg of zinc for every 800 LU of lipase activity;
- c) an amount of an *Aspergillus* derived cellulase having a cellulose hydrolyzing activity

of from about 3 CU to about 400 CU, and a manganese compound cofactor which provides manganese in a ratio of at least about 1 mg of manganese for every 400 CU of cellulase activity; and

d) an amount of an *Aspergillus* derived amylase having a starch hydrolyzing activity of from about 1,000 DU to about 20,000 DU, and a magnesium compound cofactor which provides magnesium in a ratio of at least about 1 mg of magnesium for every 20,000 DU of amylase activity.

As such, the composition can be administered to a subject in order to increase subject's ability to absorb specific types of nutrients through the hydrolysis activity induced by each pertinent enzyme. Additionally, it is noteworthy that each enzyme is accompanied by a specific catalysis enhancing mineral cofactor, in a specific cofactor to enzyme activity ratio. The specific combinations of enzyme and cofactor in the claimed composition provide for greatly enhanced activity of the enzyme, a key benefit of the present invention.

Rejection under 35 U.S.C. § 103(a) over the cited references

Claims 36-56, 62, and 64-67 were rejected as allegedly being obvious over Gorsek or Breitbarth, taken with Mochizuki, Fallon, Pabst, or Prentice; Liang, Williams, or Pero, Krumhar, Farmer, or Sachetto, Kimura, and Slaga. Applicant's submit that the present rejection is improper for at least the two following reasons: 1) each and every element of the claims is not taught in the cited references, and 2) there is no motivation to combine the references. It is well established that "[t]he PTO has the burden under § 103 to establish a *prima facie* case of obviousness." In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

As set forth above, the Examiner's present rejection of the claims relies on a numerous references the combination of which fails to teach each and every element of the pending claims. As shown by Claim 36 recited above, the present invention includes a specific combination of *Aspergillus* derived enzymes, each accompanied by a specific mineral cofactor at a required minimum ratio which enhances the catalysis activity of the enzyme. Nothing in any of the references, either individually or collectively, teaches or suggests the use of the claimed minerals as cofactors (i.e. catalysts or "lock and key" mechanisms) for unleashing the enzyme catalysis activity of the claimed *Aspergillus* enzymes. More specifically, nothing in the combination of

references links any of the specific mineral cofactors to any of the specific *Aspergillus* derived enzymes for enhancing the catalysis abilities thereof. For a summary of the teachings of each of the cited references see the Applicant's response dated April 19, 2006, pages 9-13.

The Applicants note that although the Examiner has cited references which teach an enzyme in a composition with, among other things, a mineral, none of the references taught by the Examiner teach the claimed enzymes with the claimed minerals acting as cofactors and being present in the ratios required by the claim. Applicants do not dispute that the cited references teach that: 1) enzymes are known to have co-factors, 2) some minerals are known to act as co-factors for some enzymes, 3) enzymes can be included pharmaceutical compositions, and 4) *Aspergillus* can be a source of enzymes. However, as the patentability of the presently pending claims do not rely on such teachings the cited references are ineffective in rendering the claims obvious.

In addition to the failing to teach the specific combinations of cofactors and enzymes, the cited references individually and collectively do not teach the amounts of the mineral cofactors present. Presently pending claim 36 states that each of the mineral cofactors is present at a minimum ratio with respect to the enzymes activity. Further, dependent claims 53-56 also teach specific cofactor to enzyme activity ratio ranges. Nothing in any of the cited references teaches or discloses the specific correlation of a particular cofactor with a particular enzyme nor do they disclose the ratios of cofactor to enzyme activity as disclosed above. As a result, the combination of references fails to teach each and every element of the claimed invention, and does not support a *prima facie* case of obviousness.

Additionally, it is well known that in order to reject claims using a combination of references, the Examiner must show or establish that the references themselves contain a sufficient motivation or suggestion to be combined, or that such suggestion would be found within the knowledge of one ordinarily skilled in the art. *In re Dillon*, 16 USPQ 2d 1897, 1901 (Fed. Cir. 1990). Moreover, as stated in *In re Jones*, 21 USPQ 2d 1941, 1943-44 (Fed Cir. 1992):

"....Before the PTO may combine the disclosure of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the

knowledge generally available to one of ordinary skill in the art.....

Conspicuously missing from this record is any *evidence*, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the...art would have been motivated to make the modifications of the prior art necessary to arrive at the claimed (invention)."

Applicant contends that the Examiner has failed to show sufficient motivation or suggestion to combine the inordinate number of references cited. The Examiner has relied on the well-known principle that it is *prima facie* obvious to combine elements, each of which is separately taught for the same purpose, in order to form a third composition. However, no such common purpose is taught by the references for each of the elements recited by the presently claimed invention. In fact, as can be seen from the reference summaries mentioned above, when viewed as a whole, very few of the references have any common purpose at all, and none teaches or suggests any minerals for the purpose of acting as cofactors to enhance the catalytic abilities of *Aspergillus* derived hydrolyzing enzymes. Moreover, nothing in any of the references teaches or suggests specific minerals for the purpose of being used as cofactors to improve the catalytic action of specific *Aspergillus* derived hydrolyzing enzymes to which the minerals are matched. As such, Applicant respectfully submits that no *prima facie* case of obviousness has been established, and that the combination of references is improper. Therefore, Applicant respectfully requests that the rejection be withdrawn.

Further, Applicant contends that the present combination of references has been assembled impermissibly based on hindsight reconstruction of Applicant's invention. Applicant simply cannot see any motivation to combine the inordinate number of reference outside of motivation obtained only after a review of Applicant's disclosure, and further Applicant submits that the inordinate number of references required to make the rejection acts as evidence in this regard. As can be seen from the reference summaries recited above, when viewed as a whole, each reference has very little in common with the other references, and in fact, sufficient differences exist in many cases that may qualify certain references as not analogous to the others. For example, Gorsek teaches a composition for improving ocular health, while Mochizuki teaches a composition for candying fruit. Further, Fallon teaches a method for determining whether various enzymes have a positive effect in treating PDD's and Prentice teaches

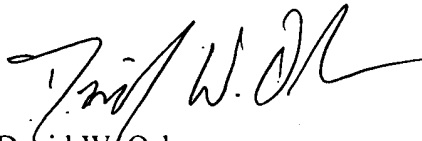
compositions and methods for making beer. Additional differences are highlighted by a comparison of Pero which teaches a composition for reducing damage to cellular DNA, and Sachetto which teaches an aerosol composition for delivery into the rectal or vaginal cavities. Moreover, as recited above, no common purpose has been established for each of the elements contained in the present claims by the combination of references, and the purpose for the minerals required by the present claims of acting as cofactors for enhancing the catalytic abilities of specific enzymes is not found in the combination of references. Accordingly, Applicant submits that the rejection is impermissibly based on hindsight reconstruction of the references in view of Applicant's disclosure, and requests that it be withdrawn.

In view of the foregoing, Applicant believes that the present rejections are unsustainable and should be withdrawn. Therefore, Applicant respectfully requests that the prosecution be reopened and/or the claims be allowed. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be resolved during a telephone interview, the Examiner is invited to telephone Mr. David Osborne, at (801) 566-6633, to address such issues as expeditiously as possible.

Dated this 15th day of January, 2007.

Respectfully submitted,

THORPE, NORTH & WESTERN, LLP

A handwritten signature in black ink, appearing to read "David W. Osborne", is written over the printed name.

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